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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/368,630	08/05/1999	DAVID M. CENTER	12875	5759

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EXAMINER

BUNNER, BRIDGET E

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 04/03/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/368,630

Applicant(s)

CENTER ET AL.

Examiner

Bridget E. Bunner

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-33, 35, 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-5, 10-11, 14-21, 23-29, 32 is/are allowed.
- 6) ☒ Claim(s) 6-9, 12, 13, 30, 31, 33, 35 and 43 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

The finality of the rejection of the last Office action (Paper No. 18, 06 June 2002) is withdrawn in view of substantial new issues, as set forth below.

Status of Application, Amendments and/or Claims

The amendment of 03 February 2003 (Paper No. 23) has been entered in full. Claim 35 is amended and claim 43 is added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-33, 35, and 43 are under consideration in the instant application.

Claim Objections

1. Claim 22 is objected to because of the following informalities: In claim 22, line 2, a space is needed between the terms "X_{aa2}" and "are". Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 6-9, 12-13, 30-31, 35, and 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-3 of U.S. Patent No.

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6,159,463 in view of IUIS/WHO Standing Committee on Interleukin Designation ("IL-16". Eur J Immunol 26: 1196, 1995). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an IL-16 antagonist peptide comprising amino acids 115-130 of IL-16/LCF (SEQ ID NO: 1 in '463). The patented species claim of a fragment of SEQ ID NO: 1 comprising amino acids 115-130 which exhibits LCF antagonist activity renders obvious the pending genus claims of an IL-16 antagonist peptide comprising $X_{aa0}RX_{aa1}X_{aa2}$ (SEQ ID NO: 1), wherein X_{aa0} is Arg or Lys, and X_{aa1} and X_{aa2} are any amino acids because amino acids 115-130 of SEQ ID NO: 1 of '463 (RRKSLQSKETTAAGDS) comprise a peptide of the formula $X_{aa0}RX_{aa1}X_{aa2}$ of SEQ ID NO: 1. Additionally, the patented genus claim of a fragment of SEQ ID NO: 1 comprising amino acids 115-130 (RRKSLQSKETTAAGDS) which exhibits LCF antagonist activity renders obvious the pending species claims of an IL-16 antagonist peptide comprising the sequence RRKS (SEQ ID NO: 2), RRKSLQ (SEQ ID NO: 17), or RRKSLQSK (SEQ ID NO: 24) because amino acids 115-130 of SEQ ID NO: 1 of '463 encompass the peptide sequences claimed in the instant application. The patented genus claim of a therapeutic composition comprising a fragment of SEQ ID NO: 1 comprising amino acids 115-130 (RRKSLQSKETTAAGDS) which exhibits LCF antagonist activity renders obvious the pending species claim of a pharmaceutical composition comprising the isolated peptide of SEQ ID NO: 24 (RRKSLQSK) and a pharmaceutically acceptable carrier because amino acids 115-130 of SEQ ID NO: 1 of '463 encompass the amino acid of SEQ ID NO: 24 claimed in the instant application. It is well known in the art that IL-16 was originally known as LCF (lymphocyte chemoattractant factor) (IUIS/WHO Standing Committee on Interleukin Designation. "IL-16". Eur J Immunol 26: 1196, 1995.)

3. Claim 33 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,807,712 in view of IUIS/WHO Standing Committee on Interleukin Designation ("IL-16". Eur J Immunol 26: 1196, 1995). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an isolated nucleic acid molecule encoding an IL-16 peptide/LCF. The patented species claim of an isolated DNA encoding a LCF polypeptide as set forth in SEQ ID NO: 1 renders obvious the pending genus claim of an isolated nucleic acid molecule encoding an isolated peptide comprising (a) $X_{aa0}RX_{aa1}X_{aa2}$ (SEQ ID NO: 1 of the instant application); $X_{aa1}X_{aa2}X_{aa0}R$ (SEQ ID NO: 8 of the instant application); or $X_{aa1}X_{aa0}RX_{aa2}$ (SEQ ID NO: 12 of the instant application), wherein X_{aa0} is Arg or Lys, and X_{aa1} and X_{aa2} are any amino acids. Specifically, the DNA encoding a LCF polypeptide as set forth in SEQ ID NO: 1 of '712 encompasses the DNA encoding the IL-16 peptide comprising the formula $X_{aa0}RX_{aa1}X_{aa2}$; $X_{aa1}X_{aa2}X_{aa0}R$; or $X_{aa1}X_{aa0}RX_{aa2}$ wherein X_{aa0} is Arg or Lys, and X_{aa1} and X_{aa2} are any amino acids (for example, please see amino acids 113-118 of SEQ ID NO: 1 of '712). It is well known in the art that IL-16 was originally known as LCF (lymphocyte chemoattractant factor) (IUIS/WHO Standing Committee on Interleukin Designation. "IL-16". Eur J Immunol 26: 1196, 1995.)

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Conclusion

Claims 2-5, 10-11, 14-21, 23-29, and 32 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

BEB
Art Unit 1647
March 31, 2003

Elizabeth C. Kemmerer

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MARCH 31 2003